

7. Auditing and Evaluation Performance Standards

- Frequency/number, quality and timeliness of reports, norms/frequency/procedures for re-audit or re-evaluation and corrective action

8. Enforcement Powers and Procedures

- Provision of written notices of violations to firms
- Non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, certificate revocation, seizure, prosecution)
- Appeal mechanisms
- Other measures to promote voluntary compliance by firm

9. Alert and Crisis Systems

- Alert mechanisms
- Crisis management mechanisms
- Alert performance standards (appropriateness and timeliness of alert)

10. Analytical Capability

- Access to laboratories with capacity to handle necessary analysis
- Standard Operating Procedures for analytical support
- Processes for validation of analytical methods